UK Biobank Ethics and Governance Council
Eighth Meeting

Meeting at Wellcome Trust
215 Euston Road London NW1 2BE

Monday 12 June 2006 at 10.30am

Agenda

1. **Apologies**

2. **Minutes** of seventh meeting held on 13 March 2006

3. **Matters arising**
(i) Public report of seventh meeting held on 13 March 2006
(ii) EGC Annual report
(iii) EGC Memorandum of Understanding
(iv) Recruitment of new EGC Chair and members
(v) Tracking of requests to UK Biobank
(vi) UK Biobank Altrincham assessment centre visits
(vii) EGC consultancy fees: Proposal for expenditure

4. **Report from UK Biobank** (Professor Rory Collins, Chief Executive, UK Biobank)
(i) Interim results of the postal feedback from integrated pilot participants

5. **Main study protocol (and associated materials)**
(i) Participant information leaflet
(ii) Supplementary information leaflet
(iii) Consent form
(iv) Main study protocol

6. **Draft EGF version 2.0**

7. **Reflections on the main study protocol and EGF discussion**

8. **Any other business**
(i) Interim arrangements and the next Council meeting

9. **Date of next meetings**
25 September 2006 - London (tbc)
4 December 2006 - London (tbc)

UK Biobank Ethics and Governance Council
Eighth Meeting

12 June 2006
Wellcome Trust, London

Summary of Meeting

Matters arising

EGC Annual report

The Council's annual report has been published and is ready for distribution.

Action: Council members were invited to inform the Secretary of individuals or organisations to whom the report should be distributed.

Recruitment of new EGC Chair and members

The deadline for applications for the position of Chair of the EGC is 14 June 2006. An appointments panel is being established by the Funders of the EGC, the Wellcome Trust and the Medical Research Council. The Panel will comprise two independent members, one of whom will act as Chair. The Panel will also have single member representation from the Board of Governors of the Wellcome Trust and of the Medical Research Council. Interviews will take place at the end of July.

The Funders are also devising an appointments strategy for the recruitment of new members. Five of the current Council members have terms of appointment which expire in November 2006.

Actions:
The Secretary will update the Council with regards to the implementation of the members' appointment strategy and regarding the outcome of the Chair recruitment process.

Members whose contracts end in November 2006 are invited to inform the Secretary of whether or not they intend to re-apply for membership.

UK Biobank Altrincham assessment centre visits

Four members of the Council and the Secretary visited the UK Biobank Altrincham assessment centre in April 2006. This provided a valuable opportunity to see how the centre runs in practice, to gain first-hand experience of the touch-screen questionnaire technology and witness the progression of participants through the recruitment process.

EGC consultancy fees: Proposal for expenditure

At the March meeting the Council identified and discussed a number of potential consultation topics which could be commissioned in order to build a theoretical and/or evidence base for the Council's advisory and monitoring functions. Informed by this debate, the EGC Chair and Secretary developed two specific commission proposals.

The proposals relate to the key function of the Ethics and Governance Council 'to keep under review applications for access to the resource with regard to the interests of research participants and in accordance with the Intellectual Property and Access Policy'. This policy states that the EGC will consider applications for access to the 'Protected Material' in advance of a decision being made by UK Biobank Board of Directors and will provide input into the decision making process. The 'Protected Material' includes any application for accessing data (in anonymised form) relating to individual participants' health, lifestyle and environment, biological samples and data derived from sample analyses or to re-contact participants.

The EGC would like to develop a framework of principles to guide its future advice and decision-making with respect to access requests to the resource. The proposed consultations are intended to inform the development of this framework:

- An academic paper will provide a theoretical base for the development of the framework. The paper will provide a conceptual analysis of the 'public interest' and 'public good' as they might be applied to UK Biobank access decision-making. This paper will be based on a literature search in the moral and political philosophy scholarly literature.
- A qualitative research project will provide an evidence base for the development of the framework. The project will provide an in-depth investigation of the public's attitudes towards how access to human genetic research databases should be managed and prioritised. The project will have a focus on access (to samples, data and participants) relating to UK Biobank, taking into account the principles, mechanisms and processes (for example, as proposed in the draft Intellectual Property and Access policy).

The Council agreed:

- To proceed with the commissioning of the academic paper.
- To postpone the commissioning of the qualitative research project until after the International Review Panel for UK Biobank has convened in July. (This will allow the proposal to be modified to take account of relevant comments made by the Panel).

A third consultation proposal arose during a discussion with the Funders. A scoping study could be commissioned investigating and summarising the work that has already been done regarding the public's attitude to UK Biobank related issues. The author of this work would be asked to look for, and report, the trends, gaps and inconsistencies in the current literature and make recommendations of areas that would benefit from further work. This would provide a solid foundation for future EGC consultation commissions. The Council approved the commissioning of this study.

The practical arrangements for commissioning work were then discussed including the methods of tender processes available and the need for the proposals to be peer reviewed.

Action: The Secretary will organise the commissioning of the academic paper and scoping study.

Report from UK Biobank (Professor Rory Collins, Chief Executive, UK Biobank)

Interim results of the postal feedback from integrated pilot participants

UK Biobank is conducting a postal survey designed to ascertain the integrated pilot participants' views on their assessment centre visit, and their opinion on UK Biobank more broadly. Results to date have indicated that:

- The assessment visit was seen as a little too long in comparison to the 60 minute duration stated in the participant information leaflet (PIL). The PIL has since been revised and now states that the visit will take approximately 90 minutes.
- The organisation of the enrolment visit was thought to work well but some refinements would remove delays further. UK Biobank has proposed an extra staff member for the main study, in order to address bottlenecks if and when they arise and to smooth out operations further.
- The PIL was thought to be clear and provide the right amount of information.
- There was a strong endorsement of the touch-screen technology used to administer the questionnaire as being easy to use.

Based on the experience of the Council members at the Altrincham assessment centre, and based on feedback that the EGC has received from an integrated pilot participant, it was recommended that:

- More attention should be paid to the (oral) privacy of participants so that interviews with participants were not overheard. This could be achieved by providing more space at the centre.
- Participants should be made aware that reasonable expenses will be paid and they should be *given* (rather than offered) an expense claim form. (The integrated pilot information leaflet does not indicate that expenses will be paid. The draft revised EGF states that 'Reasonable expenses … *may* be reimbursed as required by the participant'.) This will enhance the equality of access to UK Biobank by potential participants (if, for example, the monetary cost associated with attending the visit was a deciding factor in an individual not accepting the invite to participate).

Main study protocol (and associated materials)

The main study protocol (and associated materials) has been developed in light of the integrated pilot experience. These revised materials were considered by the Council.

Participant information leaflet

The Council has previously recommended a number of revisions to the integrated pilot participants information leaflet (PIL). The following recommendations have been incorporated into the main study protocol PIL:

- The integrated pilot PIL described UK Biobank as a 'research study'. This could mislead participants into thinking that UK Biobank will carry out research itself. It was suggested that the terminology could be reworded to convey the message that it is a resource rather than a study in and of itself.

  The revised main protocol materials describe UK Biobank as a 'medical project'. This re-wording was endorsed by the Council although labelling the project as 'medical' was thought to have possible disadvantages. This phrase suggests a more limited use of the biobank than, for example, the phrase 'health research'.

- The integrated pilot PIL stated that the resource may be accessed by companies but did not specify that these may be commercial. The revised PIL refers to 'commercial companies'.

- There should be a more clear warning that participants are signing up to the storage of specimens and information, and access to health records, for a long period of time for use by as yet unknown users of the bank. This was mentioned in the integrated pilot PIL but a concern was expressed that it is not spelled out clearly enough.

  (The main study PIL now includes this point in the section entitled 'What does taking part in UK Biobank involve?' stating that 'Agreeing to have your samples and health information stored and used (for many years) in confidence by approved researchers'.)

- The section entitled 'What happens after the assessment visit?' should state that the *full* medical record will be accessed and, if possible, more detail should be given on the types of 'other relevant records' that will be accessed.

  (The main study PIL states that 'we would like to follow the health of everyone who agrees to take part, directly through their full medical and other health-related records (e.g. occupational health)'.)

- There is some ambiguity in the integrated pilot PIL and Further Information Leaflet (FIL) about the request for additional biological samples in follow-up visits. Re-contact is presented in terms of 'more questions' and 'a similar

assessment visit'. The Council recommended that the request for more biological samples needs specifying, if that is indeed the intention.

(The main study PIL states that 'At some time in the future, participants might be re-contacted by us and asked more questions, although giving such additional help would be entirely optional. Similarly, some participants might be asked in later years to attend another assessment visit (including questions, measurements and samples), although again attendance at such visits would be optional.')

- The integrated pilot PIL states 'No' to the question 'Are there any risks for me joining UK Biobank?'. This suggests that there is zero risk associated with participation. Describing risk as 'minimal' may be more appropriate. The focus would seem to be on the risks of the appointment visit, not considering the long term nature of the resource e.g. risk of a breach in confidentiality of data. The EGC suggested including a comment on these longer-term risks in the PIL.

  (The main study PIL states that 'Participation involves a minimal risk in relation to the use of personal information. Great care will be taken to ensure the confidentiality of all data, and the risk to participants of a breach of confidentiality is considered very low'.)

- The Council recommended that the PIL could state more clearly which rights a participant is transferring to UK Biobank (ie commercial and intellectual property) in both the PIL and the FIL.

  (The main study PIL states that 'In signing the consent form, participants transfer all rights (i.e. commercial and intellectual property) in their samples and data to UK Biobank (although they may withdraw at any time).')

Further information leaflet

The Council has previously recommended a number of revisions to the integrated pilot Further Information Leaflet (FIL):

- The EGC's advisory role was mentioned in the integrated pilot FIL but its role in monitoring the resource was omitted. The Council recommended that this should be included in the main protocol FIL along with a reference to the EGC's website. This may interest participants and provide reassurance. (The main study FIL has been revised to incorporate these changes.)

- The Council recommended that more information should be provided in the section entitled 'How is the confidentiality of participants protected?' In particular, the integrated pilot FIL states that 'Information that could directly identify participants … is removed from their other study data and samples *as soon as possible* after collection'. The Council asked if it is possible to specify in any more detail how long this process will take (i.e. how soon after collection this data will be removed) and to give an indication of how many UK

Biobank staff will have access to the information that could directly identify participants (before and after coding).

Professor Collins commented that it is not easy to be very specific, other than it will be done as fast as possible. Access will be restricted to the limited numbers of staff that need access for the purposes of the project.

One further recommendation was made:

- The main study protocol states that the proposed sample handling and storage allows subsequent immortalisation of lymphocytes. The Council was of the opinion that in the eyes of the public, immortalisation of lymphocytes, in order to produce replenishable supplies of high molecular weight genomic DNA, would be seen as different from supplying a depletable sample of blood. It was recommended that this information should be included in the FIL.

The Council was of the opinion that the EGC's recommendations for the integrated pilot PIL and FIL had been well addressed by UK Biobank and dealt with as far as reasonable.

It was recommended that the main study materials would benefit from being submitted to the Plain English Campaign.

It was proposed that the main study information leaflets should be framed in terms that reflect the human rights of participants. That is, the leaflets can be used to alert people to relevant rights, for example, the right to a private life or, as it is often referred to, a right to privacy.

Consent form

The Council has previously recommended that three additions should be made to the integrated pilot consent form:

- The consent form does not make specific reference to the storage and use of biological samples. The Council recommended that this aspect should be explicit in the consent form.

  (The main study protocol consent form states 'I give permission for long-term storage and use of my blood and urine samples for research purposes'.)

- The consent form does not make specific reference to the ongoing and open ended nature of participation, for example after the loss of capacity or death of the participant. The Council recommended that this aspect should be explicit in the consent form (as a means of acquiring specific consent for, and re-emphasising to the participant, this key element of participation).

  It was agreed that the long term nature of participation should be added to two points already listed on the consent form (access to medical and other health-related records and the storage and use of blood and urine samples).

- The Council recommended adding the word ‘commercial’ to the following sentence ‘I understand that I will not benefit financially in any way from participation (for example, if this research leads to the *commercial* development of a new treatment)’. This should make it more clear that although the participant will not benefit that someone else may financially benefit from, for example, the development of new treatments.

  (This change has been incorporated into the main study consent form.)

In addition to the previous recommendations:

- A proposal was put forward that the following statement should be included in the consent form:

  - I understand that I may be re-contacted

  The main protocol PIL indicates that participants may be re-contacted ‘and asked more questions’. Such ‘questions’ could include follow-up for further measurements or samples or asking people to consent to participate in other research projects. (The Council also considered whether UK Biobank should seek explicit consent, at enrolment, for the possibility of specific consent being sought in the future for further involvement (e.g. participation in a new study). However, this was felt to be incorporated in the re-contact statement proposed above.)

  (The Council noted that the Interim Advisory Group had discussed the possibility of UK Biobank being used as a platform for recruitment into other studies. It was also noted that the EGC would monitor such application for access to the resource and to participants.)

- Three levels of withdrawal are available to participants. The Council questioned whether the consent form should state the options for withdrawal (specifically, highlighting the fact that some materials may remain in the resource after withdrawal (for example, information derived from the samples or contact details which are retained as a record of withdrawal so that individuals are not re-contacted)). The Council agreed that, on the condition that this information is available to participants in an information leaflet, it was not necessary to include this level of detail in the consent form.

- The Council recommended that the consent form explicitly states that ‘I understand that I relinquish all rights in the materials’.

  Main study protocol

The main study protocol, and its conformance with the EGF version 1.0, was discussed:

- The main protocol proposes that 25 000 participants will be followed-up during the recruitment phase and then every 2-3 years thereafter.

Professor Collins was asked to confirm whether the subset of individuals who are followed-up would be random (rather than a fixed subset of people followed-up over time) and whether re-contact would be based on baseline measurements. The selection of participants for follow-up will be random but may be stratified. The selection will not, however, be based on the genetic backgrounds of individuals.

- The policy on the provision of health information to participants was discussed:

    - The EGF version 1 states that UK Biobank will develop a policy on the 'provision of information in exceptional circumstances where a reading in the baseline laboratory analyses might indicate a serious illness for which intervention is possible'. The main study protocol indicates that limited baseline laboratory analyses will be conducted. Specifically, the protocol states that only those assays that cannot be done subsequently on samples that have been frozen (i.e., haematology) are to be performed as samples arrive at the central laboratory. The Council questioned whether results of the haematology would be fed back to participants. Professor Collins confirmed that the results of the haematology would not be fed back to individuals. Only some baseline measurements taken during the assessment visit would be fed back with reference to population standards. The EGF is being revised accordingly.

    - The EGF states that UK Biobank will have a policy on 'how to handle situations in which readings or observations, including incidental observations not relating to enrolment, lead them to suspect a health problem, such as possible melanoma, mental illness, or diabetes'. The UK Biobank Standard Operating Procedure (SOP) states that 'Any incidental findings (for example, a skin change that could be indicative of melanoma) observed by staff during the course of the assessment centre visit should be reported to the assessment centre manager (who will use reasonable professional judgement) to determine whether the participant should be informed and requested to contact their own GP'.

      The Council recommended that there should be greater clarity (i.e. a clear protocol) concerning the basis on which the manager will make their decision to refer, or not refer, the participant to their GP. Professor Collins agreed that UK Biobank will seek to clarify this aspect of the SOP.

- The Council re-iterated the need for further clarity regarding the numbers and types of UK Biobank employees who will have access to participant's personal information or access to the key which links identifying information with coded data and samples. Professor Collins commented that it was difficult to say at this stage the number of people who would have access (directly or by linking) to identifying information. Linking will be performed by computer programmes linking different sets of data. This process will, however, be managed by individuals at UK Biobank. The ability to conduct

this linking will not be based on seniority, but on the need to conduct this task as part of an individual's work duties. For example, the Steering Committee for UK Biobank, which advises the Chief Executive Officer, will not have access to personal information as this is not required by the Committee in order for it to perform its duties.

- The EGF version 1 states that UK Biobank will 'use a protocol for judging potential participants' capacity to give consent and take part in data and sample collection'. UK Biobank's SOP for this aspect of the baseline assessment centre visit states that, should any concerns arise during the consent procedure, these should be reported to the centre manager or deputy. In cases of uncertainty, the manager or deputy should suggest that the person does not participate.

  The Council advised UK Biobank to develop a more detailed protocol describing the criteria which will be used for making decisions regarding an individual's capacity to consent. The protocol should describe any specialist training that staff receive in this regard. Professor Collins agreed that UK Biobank should adopt the proposal for staff to receive training in the assessment of capacity.

- The main study protocol and the revised EGF version 2 (discussed under a separate agenda item) mention on several occasions that 'informed consent' will be obtained from individuals.

  The legal members of the Council commented that the term, 'informed consent' implies specific jurisprudential standards. Thus, while the phrase 'informed' adds little to the description of consent, it does add potential legal complications for UK Biobank. Also, from an ethical point of view, there has been considerable debate concerning whether an individual is able to give 'informed' consent to participate in a study where future uses and users of their data and samples are unknown. (The EGF describes that consent will be based on an explanation and the understanding of several element of participation in UK Biobank, including the certainties and uncertainties.) Professor Collins agreed that the qualifier 'informed' would be removed from the revised EGF and other materials.

- The main study protocol describes that a 'widely *generalisable* population' will be recruited. This is in contrast to the EGF version 1 which describes that 'as *representative* a sample as is practicable' will be recruited. Professor Collins was asked to describe the reasoning behind adopting the phrase '*generalisable'* in place of '*representative'* and to outline the practical implications of this change.

  The incongruity of using the phrase 'representative' was illustrated with reference to the process of recruitment. Given that individuals will voluntarily respond to UK Biobank's invitation to participate in the study, the cohort will not be representative of the UK population, but of those willing to participate. Further, UK Biobank may deliberately seek to make the cohort

unrepresentative by over-recruiting certain groups. By over-recruiting in this way UK Biobank aims to make the cohort more broadly generalisable.

During the recruitment phase of the project, UK Biobank will need to monitor and reflect on the profile of the cohort. This may result in certain groups being specifically targeted if they are not sufficiently represented in the cohort (for example certain ethnic groups). As the cohort develops UK Biobank will consider how much targeting is required, seeking advice from the Board of Directors of UK Biobank and from the EGC as appropriate.

Draft EGF version 2.0

The EGF has been revised by Professor Collins, with input from the Council's Secretary. The draft EGF version 2.0 was brought to the Council's attention for discussion.

The Council recommended that the following policy areas should be developed further and more detailed information provided in the EGF:

- *Confidentiality.* This could be achieved by incorporating a summarised version of the Information Technology and Data Management Protocol as an annex to the EGF.
- *Research access to data and samples.* This section will need to reflect the language of, or refer to, the Intellectual Property and Access Policy.
- *Benefit sharing.*

A number of specific matters were discussed, including:

- The EGF version 1 states that consent will be based on an explanation and understanding of several aspects of UK Biobank including 'the policy for making decisions on research access'. This element of consent has been removed from the revised EGF version 2.

  The Council discussed to what extent the details of the Access Policy should be included as part of the consent procedure (for example, should details be included in the information leaflet which all participants receive?). The Council concluded that the information leaflet should reference the Policy but does not need to describe in detail the policy for making decisions on research access. Professor Collins hopes to have the revised Access Policy available for the start of the main recruitment phase so that potential participants will have the PIL, FIL and Access Policy available to them.

- The reasons underlying the policy on the feedback of health information to participants have been revised in the EGF version 2. Professor Collins commented that the reasons for not providing feedback, listed in the EGF version 1.0, did not seem like adequate justifications. Professor Collins

suggested that the main argument against feedback of health information (either that results from measurements taken before samples are stored or later, as a result of research studies) is that counselling can not be provided to participants prior to these tests being performed.

In normal healthcare settings, tests are conducted at the individual level immediately after sample collection; they search for specific conditions or outcomes; and, in the case of genetic tests, pre- and post-test counselling is provided. But, given the lack of knowledge at recruitment about the tests that might be done in this research context, UK Biobank cannot provide pre-test counselling. Indeed, if UK Biobank was to approach individuals having found an abnormal measurement the process of re-contacting them constitutes a form of feedback (which they may or may not wish to receive).

The Council reflected on the Interim Advisory Group's discussions of this policy area and on the high quantity of public debate that this area has generated. The Council also recalled the Human Genetics Commission's view that the only individual health related information that UK Biobank should consider feeding back should be that gathered from the enrolment meeting. Further, the Commission stated that were research derived from UK Biobank to discover that a number of participants were at risk of a particular condition; this should be reported in general feedback to all participants, and the public and medical community at large.

Professor Collins has discussed the feedback of health information with the Association of British Insurers. The Association advised him that, for the purposes of insurance, if no feedback of test results is provided it is as if no test has been performed. Thus the policy of providing no individual feedback beyond the assessment centre visit will have no impact on an individual's insurance.

The Council agreed that the reasons described in the EGF for not providing feedback should be the relevant reasons. Therefore the Council did not recommend re-instating the wording as found in EGF version 1. Also, the Council was satisfied that potential participants are clearly informed of the policy of no feedback beyond the enrolment phase, since the information leaflets are explicit on this point. The Council concluded that it would keep this policy under review.

- UK Biobank's policy regarding respect for incapacitated participants' wishes was discussed. UK Biobank will not enrol potential participants who express the view that they would want to withdraw should they lose mental capacity (because this would reduce the value of the resource). If an individual decides, some time after enrolment, that they would wish to be withdrawn from the project should they lose their capacity 'the options for withdrawal would be discussed with the participant and written confirmation would be sought' (draft EGF version 2). Under this policy UK Biobank will act on the participant's written confirmation when it has been informed of the participant's incapacity (for example by a family member or legal guardian).

The Council discussed the possibility that UK Biobank could immediately withdraw an individual who has informed them that they would like to be withdrawn if they lose capacity. However, it was recognised that this would diminish the value of the resource (potentially unnecessarily as the participant may never lose capacity).

The Council endorsed the approach proposed by UK Biobank on the understanding that the participant will be explicitly informed that the onus will be placed on their family member or legal guardian to inform UK Biobank of their incapacity.

Reflections on the main study protocol and EGF discussion

In closed session the Council reflected on what was felt to be a very productive discussion with Professor Collins. The Council agreed to submit a report to the Funders for distribution to the International Review Panel. This report will summarise the discussions that have taken places at this meeting. The Council agreed that the report should highlight:

Areas in need of further policy development

- *Management of incidental findings at enrolment*
- *Capacity to consent*. The Council recommends that UK Biobank should develop a protocol describing the methods that will be employed to judge an individual's capacity to consent to participation in UK Biobank and describing how the finding of a lack of capacity will be managed.
- *Research access to data, samples and participants*. The draft Intellectual Property and Access Policy should be developed further as a priority, with guidance from the EGC as appropriate.
- *Confidentiality.* UK Biobank would be advised to incorporate more details regarding the protection of confidentiality into the EGF, including both the physical and electronic security of the data and samples. In particular, the EGF should contain information concerning the re-identification of individuals, including who has access to the 'key', and their level of seniority.

Policy areas requiring ongoing review by UK Biobank and the EGC

- *Generalisability of the UK Biobank cohort.* The Council will be concerned to be kept informed about how UK Biobank intends to prioritise recruitment in the short and long term (including the basis on which UK Biobank will make decisions regarding recruitment priorities).
- *Provision of health information to participants.*

Recommendations regarding the information leaflets, including:

- The Further Information Leaflet should explicitly mention the creation of cell lines.

- The Participant Information Leaflet should make reference to the values enshrined in the Human Rights Act 1998.
- The participant information materials should be scrutinised by the Plain English Campaign.

Recommendations regarding the consent form, including statements that:

- A participant may be re-contacted.
- A participant relinquishes his/her rights to the samples.
- Samples will continue to be used, and health records continue to be accessed, beyond an individual's loss of capacity and death.

The report will also recommend that, in developing these policies, UK Biobank would be advised to seek the support of persons who are expert in these areas of ethics and law, either in-house or through external collaboration.

Any other business

Interim arrangements and the next Council meeting

Professor Campbell will step down from the position of Chair of the EGC with effect from the 31 August 2006 in order to take up a newly founded Chair in Medical Ethics at the National University of Singapore. The Funders aim to identify a new Chair of Council prior to the departure of Professor Campbell. In the event that a new Chair has not been identified it is envisaged that the Vice Chairs would manage the September Council meeting.

Dr Doyle thanked Professor Campbell, on behalf of the Funders, for his work as Chair of the Council. He commented that as Chair he has moved the project forward in a constructive way. The Council members also praised Professor Campbell for expert Chairmanship and passed on their best wishes for his success in his next role in Singapore.

Professor Campbell concluded the meeting by thanking the Secretary, the members, and the Funders for the support he has received during his time as Chair of the EGC.

Date of next meetings

25 September 2006 - London (tbc)
4 December 2006 - London (tbc)

Appendix A

Present: Professor Alastair V. Campbell (Chair), Ms Clara Mackay, Ms Sally Smith QC (afternoon only), Professor Chris Wild, Professor Sheila McLean, Professor Ian Hughes, Professor Sandy Thomas, Ms Andrea Cook.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Caroline Stone, Medical Research Council for the whole meeting. Dr Alan Doyle for the whole meeting and Ms Tara Camm for item 5(iv) and 6 only, Wellcome Trust.

Apologies: Ms Jayam Dalal and Professor Roger Higgs for the whole day and Ms Sally Smith QC for the morning only. Baroness Finlay was also unable to attend the meeting due to disruptions to her journey.

Speakers: Professor Rory Collins (Chief Executive and Principal Investigator, UK Biobank) for agenda items 4-6 inclusive.